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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,867

Applicant(s)

DESINGER, KAI

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 May 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/868,303.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received May 21, 2007, have been fully considered by the examiner. In particular, applicant's amendment to the first sentence of the specification has provided the proper priority claim. The following is a complete response to the May 21, 2007 communication.

Election/Restrictions

Claims 14-47 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 26, 2006.

Drawings

The amendment filed May 21, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: newly added Figure 7b and the associated description added to the specification at page 23, line 9+. While the original disclosure mentions on page 7, lines 22-26 that the electrodes may "be disposed on the carrier along spaced helical lines", this description is not sufficiently precise to support newly added Figure 7b. That is, there is no disclosure of the length of the electrodes, the specific spacing between the electrodes or the alternating helical electrode members as now specifically shown in Figure 7b. Applicant would be able to claim a much more specific invention than originally disclosed if the proposed new Figure 7b were added.

Applicant is required to cancel the new matter in the reply to this Office Action.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrode arrangement having a front cylinder and strip electrodes, the strip electrodes forming helical lines (claim 4) and the strip electrode with an optical waveguide (claims 7 and 12) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to show and/or describe the particular invention embodied in these claims. It appears as though applicant is selecting from a host of disclosed features and randomly claiming combinations of the features without expressly disclosing how the different embodiments are related or even feasible. For example, Claim 1 appears to be directed to the embodiment of Figures 7-10 which shows the strip electrodes. There is no clear disclosure of a "front cylinder" at the distal end of a carrier. Rather, the front tip portion is a solid, conical member (Figures 7 and 8) or a continuous tube (Figures 9 and 10) with no delineation between a cylindrical member and an insulating carrier. It is noted that the front member (10) referred to in the specification as a "front cylinder" does not meet the description of the term "cylinder". That is, the element (10) is not in the shape of a cylinder and cannot be deemed to read on such a definition. Also, there is also no clear disclosure that the strip electrodes from this embodiment may be provided in a helical pattern. Similarly, there is no disclosure of an optical waveguide used with the embodiment having strip-shaped

electrodes mounted to a carrier having a "front cylinder", and certainly no disclosure of the strip-shaped electrodes applied directly onto an outside sheath of an optical waveguide.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 lacks antecedent basis for "the insulating outside sheath", and also depends from now canceled claim 11.

Also, the amendment to claim 12 recites "elastically an din" which should apparently read "elastically and in". Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Petruzzi et al (4,765,331).

Petruzzi et al disclose an electrode arrangement for coagulation of tissue comprising a "front cylinder" (122 – Figure 4, or front sections in Figure 2), an insulating

carrier (130) proximally located and adjoining the front cylinder, and at least two electrodes supported on the carrier. Petruzzi et al specifically teach that the carrier, and the device as a whole, may be a rigid device (see col. 11, lines 5-10). The electrodes (98A, 100A) extend parallel to the longitudinal axis of the carrier (see Figures 6, 6A and 6B). A hollow duct is provided through which an optical waveguide or visualization system may be passed (col. 7, lines 10-15). Petruzzi et al disclose various formations for the front cylinder including conical (Figure 4) and wedge shaped (Figure 2).

Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleischman et al (6,146,379).

Fleischman et al disclose a device that includes strip-shaped electrodes (202) on an insulating carrier member (200) having a front cylinder member (see Figure 40). Figures 40-50 show several embodiments for the strip-shaped electrodes, including diametrically opposing electrodes (Figure 45) and a metal tube embodiment having and exposed electrode (Figures 49-50). Fleischman also teach the electrodes may be provided in a helical configuration (Figures 38, 47 and 48). Figures 40-45 show the electrodes applied as thin conductive strips on the carrier, and the terms "rigid" and "flexible" in claims 11 and 13 are broad enough that the Fleischman et al device is deemed to meet either one. That is, the device is clearly flexible and may be shaped to create lesions of a desired pattern, but is also rigid enough to be inserted through tissue to reach the desired treatment location.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi et al ('331) in view of the teaching of Fleischman et al ('379).

Petruzzi et al disclose various arrangements for the electrodes on the carrier member, but fail to specifically disclose helical electrodes for the treatment of tissue.

As addressed previously, Fleischman et al disclose an electrode device for the treatment of tissue and specifically disclose that it is known to provide the electrodes in a variety of arrangements including parallel (Figure 45) and helically wound electrodes (Figures 38, 47 and 48) to provide a desired heating profile to tissue.

To have provided the Petruzzi et al electrodes with any desired arrangement, such as helically wound, to provide the desired heating profile would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Fleischman et al.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al ('379) in view of the teaching of Chen et al (6,358,249).

The Fleischman et al device has been addressed previously. Fleischman et al teach of electrodes made from various materials, including layers of titanium, but fail to

disclose the insulating materials as set forth in these claims. The examiner maintains that the use of any well known material for making medical grade electrodes is generally well-known in the art and a matter of obvious design consideration. Further, it is noted that applicant's specification fails to provide any criticality or unexpected results associated with the selected materials.

Chen et al is cited as a general teaching that it is known to make electrodes from various metals as well as the use of aluminum-oxide layers as insulation (see col. 9, lines 60+) for electrodes in an electrosurgical device.

To have provided the Fleischman device with any well-known insulation material to insulate the electrode members would have been an obvious design consideration for one of ordinary skill in the art, particularly in view of the teaching of Chen et al who disclose the use of aluminum oxide as an insulating material.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al ('379) in view of the teaching of Laufer (6,036,687).

Fleischman et al disclose various embodiments for the catheter device, but fail to specifically disclose the conical or wedge shaped tip members as recited in claims 8 and 9.

The examiner again maintains that tip members are generally known to come in a variety of shapes to facilitate the specific use of the device. That is, catheters may have rounded tips to facilitate passage through the vasculature without rupturing the vasculature, or may have conical or wedge shaped tips to facilitate passing the device

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through tissue or through a blockage in the vasculature. Fleischman et al teach of providing a sheath having a penetrating tip to advance the catheter into select tissue sites, but fails to disclose a catheter having a specific conical or wedge shaped tip.

Laufer et al disclose an analogous catheter device, and specifically teach that the catheter may have a rounded tip (e.g. Figures 8-10) or may have a more pointed conical or wedge shaped tip (Figures 17 and 19) to facilitate it's placement into particular tissue locations.

The examiner maintains that it would have been an obvious design consideration for one of ordinary skill in the art to provide the Fleischman et al catheter with a wedge or conical-shaped tip member to facilitate its placement into a particular tissue location, particularly since Fleischman et al disclose the device is used in procedures that require the penetration of tissue and further in view of the teaching of Laufer et al who teach that it is known to provide a catheter with a more sharpened distal tip to facilitate placement in tissue.

Response to Arguments

Applicant's arguments filed May 21, 2007 have been fully considered but they are not persuasive.

Regarding the Drawing Objection and the 35 USC 112, First Paragraph rejection involving the "front cylinder", the examiner maintains that while the specification does make reference to element (10) as a "front cylinder", there is no way to conclude from the drawing that element (10) is in any way a "cylinder". It shape of element (10), which is clearly a conical member, does not meet any definition of a cylinder. This creates

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uncertainty, particularly in the claims, since one of ordinary skill in the art reading the claims would not look to element (10) in Figures 7 and 8 to fit within the description of a "cylinder". The examiner maintains that the specification and figures fail to show and describe the claimed invention that includes a "front cylinder" having strip electrodes on a proximally adjoining carrier as one would reasonably understand the meaning of the terms. The examiner has, nonetheless, applied art that appears to read on the structure shown and described in the specification.

With regard to the "optical waveguide", the examiner maintains that the drawings and specification fail to provide support for the claimed subject matter. While Figures 9 and 10 include strip electrodes on an optical waveguide, there is no "front cylinder" in either of these embodiments. Independent claim 1, and dependent claim 12 which recites the optical waveguide, require a device having a "front cylinder" and an electrically insulating carrier proximally adjoining the front cylinder. Figures 9 and 10 fail to show the front cylinder, and there is no drawing or description in the specification that supports a device having a front cylinder and a carrier comprising an optical waveguide.

Concerning the helical pattern for the electrodes, the examiner maintains as asserted above that proposed Figure 7b and the associated description in the specification would constitute new matter. The specification failed to provide a sufficiently detailed description of the helical electrodes to fully support the proposed drawing. In particular, the spacing, length and alternate location of the electrodes along the length were not specifically addressed. The specification did state that the electrodes could be helically spaced along the length. However, it was not explicit as to

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the spacing, or even the arrangement of the electrodes. For example, the language in the specification may equally support a first electrode helically mounted on the carrier, and a second electrode helically mounted proximally of the first electrode as opposed to the alternating helices of electrodes as shown in Figure 7b. Figure 7b provides additional details that, if entered, would allow applicant to claim subject matter not previously disclosed.

Concerning the art rejections, applicant has only addressed the Fleischman et al reference. In particular, applicant contends that the Fleischman et al reference is referred to throughout the disclosure as “flexible” and could not be considered “rigid”. The examiner maintains, as pointed out in the previous Office action, that the terms “rigid” and “flexible” are very subjective. While the Fleischman et al device is used to create curved lesions, being curved, or capable of being curved, does not necessarily mean a device can not also be “rigid” within the broadest reasonable interpretation of the term. Further, the claim recites that “the carrier comprises rigid material” (emphasis added). This is not explicitly stating the carrier “is rigid”. The examiner maintains that all embodiments of the Fleischman et al device include a carrier that comprises a rigid material, whether it is a “rigid” ring electrode, or a steering wire, or the metal tube used to make the tubular structure (i.e. Figures 49 and 50). In each of these instances, at least part of the insulating carrier portion has a material that is rigid in at least one of compression or bending forces. Applicant’s specification fails to provide any specific definition for what is meant by “rigid”, particularly given that the term is relative

especially in the medical field. As such, the examiner maintains that the Fleischman et al structure continues to read on the rejected claims.

Finally, applicant notes that Figure 48 of Fleischman et al fails to disclose multiple electrodes that can be operated in a bipolar mode. The examiner maintains that the Fleischman et al reference provides several unipolar and bipolar embodiments and expressly states throughout the specification that unipolar and bipolar embodiments are readily substituted. Moreover, Figures 37 and 38 specifically show unipolar and bipolar helical electrodes further supporting the fact that Fleischman et al fully disclose bipolar helical electrodes. The examiner maintains the rejection is tenable.

Applicant has not argued any of the obviousness rejections involving the Fleischman et al reference. The examiner maintains that these rejections are tenable and they are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner
Art Unit 3739

/mp/
July 24, 2007